AUG 20 2012

K120486

510(k) Summary: AVS® AS PEEK Spacer	
Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Ms. Soraya King Regulatory Affairs Specialist Phone: 201-760-8296 Fax: 201-962-42496 Email: Soraya.King@stryker.com
Date Prepared	August 2, 2012
Trade Name	AVS® AS PEEK Spacer
Common Name	Intervertebral Body Fusion Device
Proposed Class	Class II
Classification Name and Number	Intervertebral body fusion device, 21 CFR 888.3080
Product Code	ODP
Predicate Devices	The AVS® AS PEEK Spacer was shown to be substantially equivalent to the device listed below: • ORTHOVITA PEEK SPACER, 510(k) #K101171
Device Description	The Stryker Spine AVS® AS PEEK Spacer is a hollow, ring-shaped PEEK Optima® LT1 cage (per ASTM F2026) with three Tantalum marker pins (per ASTM F560). It is intended for use as an interbody fusion device of the cervical spine and is offered in a variety of lengths, heights, and lordotic angles to adapt to varying patient anatomies. The hollow, ring-shaped implant has serrations on the top and bottom for fixation. The hollow space of the implant is intended to hold bone graft material for fusion purposes.
Intended Use	The Stryker Spine AVS® AS PEEK Spacers are indicated for use in cervical interbody fusion procedures in skeletally mature patients with

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	degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AVS® AS PEEK Spacers are to be used with autogenous bone graft and implanted via an open, anterior approach. The AVS® AS PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment.
Summary of the Technological Characteristics	The subject AVS® AS PEEK Spacer and the predicates share similar design features: • Graft windows for packing autogenous bone • Serrations on the superior and inferior surfaces • Comparable heights, widths, depths, and lordotic angles Testing in compliance with FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the AVS® AS PEEK Spacer implants and demonstrated substantially equivalent performance to the identified predicate device systems. The following mechanical tests were performed: • Static Compression (per ASTM F2077) • Static Compression Shear (per ASTM F2077) • Static Torsion (per ASTM F2077) • Subsidence (per ASTM F2267) • Dynamic Compression (per ASTM F2077) • Dynamic Compression Shear (per ASTM F2077) • Dynamic Torsion (per ASTM F2077)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Stryker Spine
% Ms. Soraya King
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K120486
Trade Name: Stryker Spine AVS® AS PEEK Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP
Dated: August 02, 2012
Received: August 03, 2012

Dear Ms. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120486

Indications for Use

510(k) Number (if known): K120486

Device Name: Stryker Spine AVS® AS PEEK Spacers

Indications For Use:

The Stryker Spine AVS® AS PEEK Spacers are indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AVS® AS PEEK Spacers are to be used with autogenous bone graft and implanted via an open, anterior approach.

The AVS® AS PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120486